Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Re-evaluation Decision RVD2018-32

Azadirachtin and Its Associated End-use Product

Final Decision

(publié aussi en français)

15 October 2018

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2018-32E (print version)
H113-28/2018-32E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2018

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Azadirachtin is a systemic insecticide registered for commercial use to control insect pests of trees in forest, woodlot, urban and residential landscapes. Azadirachtin can be applied as a tree trunk injection using the EcoJect Tree Injection System. Currently registered products containing azadirachtin are listed in Appendix I.

This document presents the final regulatory decision[1] for the re-evaluation of azadirachtin. All pest control products containing azadirachtin that are registered in Canada are subject to this re-evaluation decision. Prior to finalizing this decision, Health Canada published the Proposed Re-evaluation Decision PRVD2018-10, *Azadirachtin and Its Associated End-use Product*,[2] for 90-day consultation.

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2018-10.

A reference list of all data used as the basis for the re-evaluation decision is included in PRVD2018-10.

Regulatory Decision for Azadirachtin

Health Canada has completed the re-evaluation for azadirachtin. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing azadirachtin is acceptable. Following a scientific review of the available information, Health Canada has determined that the health and environmental risks and the value of azadirachtin continue to be acceptable when used according to label directions. No additional data or label amendments are required at this time.

1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

2 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[3] regarding this decision on azadirachtin within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Registered Azadirachtin Products in Canada[1]

Registration No.	Marketing Class	Registrant	Product Name	Formulation	Guarantee (%)
30558	Technical Grade Active Ingredient	Coromandel International Limited	NeemAzal Technical	Dust	36.65%
30559	Commercial	BioForest Technologies Inc.	TreeAzin Systemic Insecticide	Solution	5%

[1] As of 20 August 2018.